

PTO/SB/21 (01-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PW

## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

|  |                      |                        |          |
|--|----------------------|------------------------|----------|
|  | Application Number   | 10/810,388             |          |
|  | Filing Date          | March 26, 2004         |          |
|  | First Named Inventor | SHAW et al.            |          |
|  | Art Unit             | 1614                   |          |
|  | Examiner Name        |                        |          |
| Total Number of Pages in This Submission | 80                   | Attorney Docket Number | 5853-400 |

| ENCLOSURES (Check all that apply)  |   |  |  |
|--|---|--|--|
| <input type="checkbox"/> Fee Transmittal Form  | <input type="checkbox"/> Drawing(s)                                       | <input type="checkbox"/> After Allowance Communication to Group                            |  |
| <input type="checkbox"/> Fee Attached  | <input type="checkbox"/> Licensing-related Papers                         | <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences        |  |
| <input type="checkbox"/> Amendment/Reply   | <input type="checkbox"/> Petition   | <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) |  |
| <input type="checkbox"/> After Final   | <input type="checkbox"/> Petition to Convert to a Provisional Application | <input type="checkbox"/> Proprietary Information   |  |
| <input type="checkbox"/> Affidavits/declaration(s)   | <input type="checkbox"/> Power of Attorney, Revocation                    | <input type="checkbox"/> Status Letter   |  |
| <input type="checkbox"/> Extension of Time Request   | <input type="checkbox"/> Change of Correspondence Address                 | <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):            |  |
| <input type="checkbox"/> Express Abandonment Request   | <input type="checkbox"/> Terminal Disclaimer                              |  |  |
| <input checked="" type="checkbox"/> Information Disclosure Statement                               | <input type="checkbox"/> Request for Refund                               |  |  |
| <input type="checkbox"/> Certified Copy of Priority Document(s)                                    | <input type="checkbox"/> CD, Number of CD(s)                              |  |  |
| <input type="checkbox"/> Response to Missing Parts/Incomplete Application                          |   |  |  |
| <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53                       |   |  |  |
| Remarks  |   |  |  |
| Postcard   |   |  |  |
| No fees are believed necessary, but please charge any deficiencies to Deposit Account No. 50-0951. |   |  |  |

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

|                    |  |
|--------------------|--|
| Firm or Individual | AKERMAN SENTERFITT<br>Gregory A. Nelson, Registration No. 30,577 |
| Signature          |  |
| Date               | 2-16-05  |

### CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date:

|                  |                   |
|------------------|-------------------|
| Typed or printed | Gregory A. Nelson |
| Signature        |                   |
| Date             | 2-16-05           |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of SHAW et al.

Application No. 10/810,388

Examiner:

Filed: March 26, 2004

Group Art Unit: 1614

For: ASSESSING NEURONAL DAMAGE FROM BLOOD SAMPLES

**INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 CFR §1.97(b)**

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Alexandria, VA

22313-1450 on  
Reg. No. 30,577  
Signature of Gregory A. Nelson

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to the Duty to Disclose under 37 C.F.R. §1.56, the references cited on the accompanying form PTO/SB/08B are hereby brought to the attention of the Examiner for independent evaluation. The enclosed documents were cited in the specification of the present application.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Applicant respectfully requests that the listed documents be considered by the Examiner and made of record in the present application and that an initialed copy of form PTO/SB/08B be returned in accordance with MPEP §609.

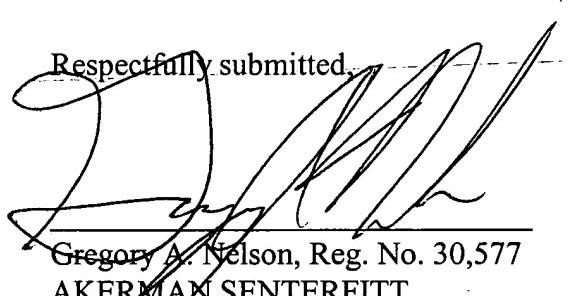
Certification

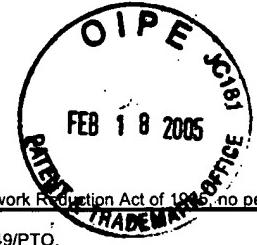
This Statement is being filed within three months of the filing of this application and/or prior to the issuance of the first Office Action for the present application, and this paper is thus submitted in accordance with 37 CFR §1.97(b). In view of this certification, a fee is not required for consideration of these documents. Nevertheless, should a fee be deemed to be due by the Commissioner, such fee should be charged to Deposit Account No. 50-0951.

Dated: 2-16-05

Docket No. 5853-400

Respectfully submitted,

  
\_\_\_\_\_  
Gregory A. Nelson, Reg. No. 30,577  
AKERMAN SENTERFITT  
Post Office Box 3188  
West Palm Beach, FL 33402-3188  
Telephone: (561) 653-5000



PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO.

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

### Complete if Known

|       |   |    |   |                        |                |
|-------|---|----|---|------------------------|----------------|
|       |   |    |   | Application Number     | 10/810,388     |
|       |   |    |   | Filing Date            | March 26, 2004 |
|       |   |    |   | First Named Inventor   | SHAW et al.    |
|       |   |    |   | Art Unit               | 1614           |
|       |   |    |   | Examiner Name          |                |
| Sheet | 1 | of | 1 | Attorney Docket Number | 5853-400       |

### NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|--------------------|-----------------------|---|----------------|
|                    |                       | DELACOURTE et al. Study of the 10-nm-Filament Fraction Isolated During the Standard Microtubule Preparation: Biochem Journal. 1980, Vol 191, pages 543-546  |                |
|                    |                       | WEBER et al. Tissue Polypeptide Antigen (TPA) is Related to the Non-Epidermal Keratins 8, 18 and 19 Typical of Simple and Non-Squamous Epithelia: Re-evaluation of a Human Tumor Marker. The EMBO Journal. 1984, Vol. 3, No. 11, pages 2707-2714                |                |
|                    |                       | PERSSON et al. S-100 Protein and Neuron-Specific Enolase in Cerebrospinal Fluid and Serum: Markers of Cell Damage in Human Central Nervous System. Stroke. 1987, Vol. 18, No. 5, pages 911-918  |                |
|                    |                       | INGEBRIGTSEN et al. Biochemical Serum Markers of Traumatic Brain Injury. The Journal of Trauma Injury, Infection, and Critical Care. 2002, Vol. 52, pages 798-808   |                |
|                    |                       | BJORKLUND, B. Tissue Polypeptide Antigen (TPA): Biology, Biochemistry, Improved Assay Methodology, Clinical Significance in Cancer and Other Conditions, and Future Outlook. Antibiotics Chemotherapy. 1978, Vol. 22, pages 16-31                               |                |
|                    |                       | TOGO et al. Tau Accumulation in Astrocytes in Progressive Supranuclear Palsy in a Degenerative rather than a Reactive Process. Acta Neuropathol. 2002, Vol. 104, pages 398-402  |                |
|                    |                       | NAM et al. Nanoparticle-Based Bio-Bar Codes for the Ultrasensitive Detection of Proteins. Science. 2003, Vol. 301, pages 1884-1886  |                |
|                    |                       | ZEMLAN, et al. Quantification of Axonal Damage in Traumatic Brain Injury: Affinity Purification and Characterization of Cerebrospinal Fluid Tau Proteins. Journal of Neurochemistry. 1999, Vol. 72, No. 2, pages 741-750  |                |
|                    |                       | PIKE et al. Accumulation of Calpain and Caspase-3 Proteolytic Fragments of Brain-Derived II-Spectrin in Cerebral Spinal Fluid After Middle Cerebral Artery Occlusion in Rats. Journal of Cerebral Blood Flow and Metabolism. 2004, Vol. 24, No. 1, pages 98-106 |                |
|                    |                       |   |                |

|                    |  |                 |  |
|--------------------|--|-----------------|--|
| Examiner Signature |  | Date Considered |  |
|--------------------|--|-----------------|--|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:  
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.